UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BAXTER HEALTHCARE CORPORATION,

Plaintiff,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK,

Defendant.

CIVIL ACTION No.

03 CV 12221 MLW

MAGISTRATE JUDGE Bowler

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY AND UNENFORCEABILITY OF U.S. PATENT NO. 6,455,275, AND THAT NO ROYALTIES ARE OWED

I. INTRODUCTION

1. Twenty years ago in 1983, defendant The Trustees of Columbia University in the City of New York ("Columbia") obtained a patent on a recombinant DNA technology called "cotransformation." In 1987 and 1993, Columbia obtained two additional related patents based on the same research and claiming substantially the same invention as its first cotransformation patent. Last year, and two years ***after*** the expiration of the three related patents, Columbia obtained yet another related cotransformation patent. Columbia now is attempting to use this new patent to extend its patent monopoly for a second seventeen-year period. Plaintiff Baxter Healthcare Corporation ("Baxter") brings this action for a declaration that Columbia has no lawful right to receive royalties from its licensees, including Baxter, based on its newly-issued cotransformation patent, because that patent is invalid and unenforceable.

2. Cotransformation is a process for inserting foreign DNA into a host cell to produce certain proteins. Columbia's first cotransformation patent, U.S. Patent No. 4,399,216 (the "'216 patent"), issued in August 1983. Its second and third patents, U.S. Patent Nos. 4,634,665 (the "'665 patent") and 5,179,017 (the "'017 patent"), issued in 1987 and 1993, respectively. All three patents originated from a single patent application filed by Columbia on February 25, 1980, and were based upon the same experimental research described in that application. Because the United States Patent and Trademark Office ("Patent Office") determined that the second and third of Columbia's cotransformation patents claimed substantially the same invention as the first, and thus constituted impermissible "double-patenting," the Patent Office required Columbia to file terminal disclaimers to disclaim any rights in those patents extending beyond the expiration date of the first issued patent. As a result, all three patents expired the same day, August 16, 2000.

3. Columbia licensed its first three cotransformation patents to over thirty biotechnology companies and received hundreds of millions of dollars in royalty payments from those companies before the patents expired in 2000. Shortly before the expiration of the patents in 2000, Columbia lobbied Congress to obtain a fifteen month extension of the term of its original cotransformation patent. The result of such an extension would have been millions of dollars in additional royalty payments to Columbia from its licensees. Congress rejected Columbia's lobbying effort, and all three patents expired that year.

4. At the same time, Columbia secretly was prosecuting still more patent applications on its cotransformation technology. Columbia filed these applications in 1995, but delayed prosecuting them through a variety of procedural tactics. By misleading the Patent Office about the claim scope of its earlier cotransformation patents, Columbia obtained a fourth

cotransformation patent, U.S. Patent No. 6,455,275 B1 (the "'275 patent") on September 24, 2002. The term of the new patent extends another seventeen years to 2019, even though based on the *same* research described in the original 1980 patent application. Columbia has now demanded royalties on the new '275 patent from the companies that had licensed the earlier cotransformation patents. Because Columbia's new cotransformation patent is invalid and unenforceable, as explained below, this Court should grant declaratory and injunctive relief preventing its enforcement against Baxter.

II. PARTIES

5. Baxter is, and at all relevant times has been, a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. Baxter, a world leader in replacement blood product therapies, is engaged in the research, development, production, and sale of recombinant Factor VIII (a therapy for people suffering hemophilia A), including Baxter's Recombinate™ and Advate™ products. Genetics Institute LLC (formerly known as Genetics Institute, Inc.) ("GI"), a wholly-owned subsidiary of Wyeth, has manufactured bulk recombinant Factor VIII in Massachusetts and supplied it to Baxter under a supply agreement for more than a decade. In 1990, GI entered into a license agreement with Columbia (the "GI License Agreement"), to obtain rights to use the cotransformation technology that Columbia patented. Under its supply agreement with GI, Baxter is responsible for a significant portion of the royalties GI pays to Columbia under the GI License Agreement for recombinant Factor VIII supplied to Baxter. In the aggregate, Baxter's share of royalties paid to Columbia to date under the GI License Agreement has amounted to more than $5 million. In addition, in 1997 Baxter entered into a license agreement with Columbia (the "Baxter License Agreement") with respect to Columbia's

patented cotransformation technology, under which Baxter pays royalties to Columbia on recombinant Factor VIII that Baxter itself manufactures.

6. Defendant Columbia is a New York non-profit corporation with a principal place of business in New York, New York. It is the owner by assignment of the various cotransformation patents relevant to this action, including the '216 patent, the '665 patent, the '017 patent, and the '275 patent, all licensed to Baxter under the Baxter License Agreement. Columbia also is the owner by assignment of U.S. Patent No. 5,149,636 ("'636 patent").

III. JURISDICTION AND VENUE

7. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202. Also, because the amount in controversy exceeds $75,000, and the action is between citizens of different states, the Court has jurisdiction under 28 U.S.C. § 1332(a)(1).

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b).

IV. FACTS

A. Columbia's Original Cotransformation Patent Application

9. In the late 1970s, Richard Axel, Michael H. Wigler, and Saul J. Silverstein, scientists at Columbia University, carried out research on methods of inserting genes that encode certain proteins into the DNA of certain types of eukaryotic host cells. Specifically, the Columbia scientists conducted experiments in cotransformation, a process of altering the genotype of a eukaryotic "recipient" cell by inserting into the cell both (a) a gene that codes for a desired protein and (b) a gene that codes for a "selectable marker." A selectable marker is a gene the expression of which confirms that the cell has been successfully transformed. If the selectable marker has been incorporated into the host cell's nuclear DNA, it is likely that the cell has also incorporated the gene coding for the desired protein.

10. Axel, Wigler, and Silverstein ("Axel *et al.* ") filed a patent application in February 1980. This application, Serial No. 06/124,513 (the "'513 application"), assigned to Columbia, issued as the '216 patent on August 16, 1983. The '216 patent has 73 claims, broadly covering (a) processes for cotransforming cells, (b) processes for producing and recovering protein from a cotransformed cell, (c) processes for detecting cotransformed cells, and (d) cotransformed cells. It had a term of seventeen years from the date of issuance and expired on August 16, 2000.

11. The research that led to the '216 patent was funded by the National Institutes of Health ("NIH"). NIH granted title to the invention to Columbia under certain conditions. One of the conditions was that any license "shall include adequate safeguards against unreasonable royalties and repressive practices. Royalties shall not in any event be in excess of normal trade practice."

B. Columbia's Additional Patent Applications

12. Shortly before the '216 patent issued in 1983, Columbia filed a continuation application, Serial No. 06/522,408 (the "'408 application"), which relied on the same specification as the '513 application that issued as the '216 patent.

13. In January 1987, after almost three and one-half years of prosecution, the Patent Office allowed claims in the '408 application and issued the '665 patent. The '665 patent claims (a) processes for cotransforming cells, (b) processes for producing and recovering protein from a cotransformed cell, and (c) cotransformed cells. Because these claims of the '665 patent were not patentably distinct from the claims of the '216 patent, the Patent Office required Columbia to file a terminal disclaimer disclaiming the portion of the patent's term that would have extended past the expiration date of the '216 patent.

14. On October 3, 1986, Columbia filed another continuation application, Serial No. 06/915,273 (the "'273 application"), based on the specification of the '216 patent. Columbia abandoned this application after two years of prosecution and filed another continuation application, Serial No. 07/346,089 (the "'089 application"), on May 2, 1989. Columbia then abandoned the '089 application after three years in favor of yet another continuation application, Serial No. 07/716,915 (the "'915 application"), filed on June 18, 1991.

15. In the '915 application, Columbia attempted to obtain claims to transformed CHO cells. The Patent Office allowed those claims to issue as the '017 patent after Columbia filed a terminal disclaimer limiting the term of the '017 patent to the term of the original '216 patent. In all, the '216, '665, and '017 patents contain more than 100 claims, all originating from Columbia's original patent application filed in 1980.

16. Columbia continued to file continuation applications based on the original specification, but abandoned most of those continuation applications. By repeatedly filing new applications based on the original specification and research and abandoning them, Columbia kept the original specification alive to obtain new patents that cover the latest developments in the biotechnology industry. This practice, called "submarine" patenting, allowed Columbia to abuse the patent system by "surfacing" with the new '275 patent many years after the original application was filed.

17. Effective June 8, 1995, Congress reformed the patent law to close the loopholes that had made submarine patenting possible. On June 7, 1995, the day before this change in the law went into effect, Columbia secretly filed two further continuation applications based on the original specification. In September 2002, one of these applications, Serial No. 08/484,136 (the "'136 application") issued after numerous amendments as the '275 patent now in suit. Because

Columbia did not file a terminal disclaimer with respect to the '275 patent, it will not expire until 2019. Indeed, Columbia opposed the filing of a terminal disclaimer, knowing that if it did so, the patent would effectively expire before it issued. Another application, filed the same day as the '136 application, Serial No. 08/477,159 ("the '159 application"), is still pending at the Patent Office.

C. Columbia's '636 Patent

18. On information and belief, at about the same time or shortly after Axel *et al.* completed the research on which the original '513 application was based, Axel and another researcher carried out further research on methods of cotransforming eukaryotic cells with foreign DNA encoding genes for producing desired proteins, which was closely related to the work that had led to the '216, '665, and '017 patents. Columbia filed a separate patent application on March 15, 1982, Serial No. 358,206 (the "'206 application"), instead of filing a continuation application or a continuation-in-part application. After filing two more continuation applications, Columbia obtained U.S. Patent 5,149,636 (the "'636 patent") on September 22, 1992, more than a decade after it filed the initial '206 application. Columbia never disclosed the '636 patent or its file history to the examiner in the '275 patent prosecution so that the examiner could make a determination of its materiality to the patentability of the '275 patent.

D. Columbia's Licensing of the Axel Patents

19. Columbia has granted non-exclusive licenses under the '216, '665, and '017 patents (and continuations thereof) to over thirty biotechnology companies, including GI and Baxter. Pursuant to a supply agreement dated July 31, 1989, as amended and restated in 1999 and 2001, GI manufactures certain bulk recombinant Factor VIII for Baxter. Baxter purchases such bulk Factor VIII and formulates, finishes, and sells the final product, Recombinate™.

Pursuant to a royalty-sharing provision contained in the supply agreement, Baxter is responsible for a significant portion of the royalties paid to Columbia by GI under the GI License Agreement for the manufacture of bulk recombinant Factor VIII supplied to Baxter.

20. In addition, Columbia granted a non-exclusive license under the '216, '665, and '017 patents (and continuations thereof) to Baxter in October 1997. The Baxter License Agreement provided for an up-front payment to Columbia and royalties on sales of licensed products. The Baxter License Agreement further provided for minimum annual payments regardless of sales of licensed products.

21. The Baxter License Agreement required Baxter to pay royalties not only on Columbia's issued patents such as the '216 patent, but also on patents issuing from "any and all divisions, continuation application and continuations-in-part" thereof (that cover any licensed products). This provision, and the same or similar provision in its license agreements with other biotechnology companies, provided an incentive for Columbia to extend the patent protection on the cotransformation technology for as long as possible. Columbia's license agreements with Baxter, GI, and other biotechnology companies have generated hundreds of millions of dollars in royalties for Columbia.

E. Columbia's Failed Attempt to Obtain a Patent Term Extension

22. The '216, '665, and '017 patents expired in August 2000. Shortly before they were due to expire, Columbia lobbied Congress to obtain an extension for the term of the '216 patent. On information and belief, Columbia claimed that the income stream from the patent was critical and an important source of funding for the university. At the same time, the university claimed that the biotechnology industry was not burdened by paying these royalties, which Columbia characterized as "nominal."

23. On information and belief, Columbia described its '216 patent to Congress as pioneering and as covering both the cotransformed cells and the process for transforming animal cells to produce proteins used in biological pharmaceutical products. According to Columbia, it was the '216 patent that "makes it possible to generate the cell lines that are needed to produce patented drugs." As Columbia told Congress, its patent broadly claimed both "the cotransformed cells and the process of making them."

24. While Columbia requested urgent action on its patent term extension request, it did not tell Congress that it was simultaneously prosecuting secret patent applications that sought the issuance of new patents claiming the same, original cotransformation technology, each with new seventeen-year terms. At the same time, Columbia did not tell the Patent Office that it believed the '216 patent to have extremely broad claim scope.

25. Columbia's request for extension of the term of the '216 patent met with widespread public disapproval, and Congress rejected it. The cotransformation inventions claimed in the '216, '665, and '017 patents passed into the public domain in August 2000, and all biotechnology companies were free to develop and sell recombinant biological products utilizing such inventions without the burden of paying further royalties to Columbia.

F. The '275 Patent

26. Columbia had an alternative plan to extend the term of its patent protection over the cotransformation technology. In 1995, Columbia secretly filed two additional patent applications relying on the same patent specification that had been the basis for the '216, '665, and '017 patents.

27. These continuation applications were the last Columbia could file under the pre-reform patent prosecution rules, and thus Columbia could not simply abandon them and file new

continuation applications, which would have expired in February 2000 under the new rules. Instead, Columbia employed procedural delays to keep its continuation applications pending, including filing for extensions and filing notices of appeal to gain additional time.

28. Using these tactics, Columbia extended the prosecution of the two continuation applications. The application leading to the '275 patent did not mature into a patent until more than seven years after its filing date, issuing on September 24, 2002, almost twenty-three years after the filing of the original specification and more than two years after the three earlier cotransformation patents expired. It was the product of ***eight*** continuation or divisional applications, of which five were abandoned. During prosecution of the '275 patent, which began fifteen years after Columbia filed the original application, Columbia sought extensions of time amounting to twenty-two months, filed two notices of appeal that it did not pursue, and added many new claims at a late stage in the prosecution. The other application is still pending eight years after filing.

29. In addition, Columbia also misled the patent examiner to obtain the '275 patent, as set forth below. The '275 patent claims developments in biotechnology the Columbia researchers either had not achieved or had been unaware of at the time they filed the original application in 1980. It claims (a) transformed CHO cells, a cell type that the inventors had never used successfully as a vehicle for the production of medically valuable proteins; (b) methods of producing and recovering protein materials that the inventors had not practiced at the time they filed the original application; and (c) a "DNA construct," a term that does not appear in the original specification and came into use in the biotechnology industry after the original 1980 priority filing date.

30. Unlike the '665 and the '017 patents, however, the '275 patent issued without a terminal disclaimer. Thus, if valid and enforceable, the '275 patent would not expire until ***September 2019.*** The combined terms of the new patent and the '216 patent would run for two full seventeen-year patent terms, from 1983 to 2019 (with a two-year gap between the expiration of the '216 patent and the issuance of the '275 patent). This combined term is twice as long as the seventeen years originally permitted with the issuance of the '216 patent.

G. Columbia's Recent Demands Under the License Agreements

31. Shortly after the '275 patent issued, Columbia announced to Baxter and other licensees that the issuance of the '275 patent triggered the obligation to pay royalties under the license agreements for another seventeen years, the term of the '275 patent. On information and belief, Columbia has demanded royalties from GI based on the GI License Agreement, a significant portion of which would be the responsibility of Baxter for recombinant Factor VIII supplied to Baxter under its supply agreement with GI.

V. CLAIMS

Count I: Declaratory Judgment That GI Owes No Royalties Under the GI License Agreement with Respect to the '275 Patent

32. Baxter incorporates all prior paragraphs of this complaint.

33. On information and belief, Columbia contends pursuant to the GI License Agreement that GI must pay royalties under the '275 patent. Under its supply agreement with GI, Baxter is responsible for a significant portion of royalties GI pays to Columbia under the GI License Agreement for recombinant Factor VIII supplied to Baxter. Baxter contends that GI has no obligation to pay such royalties because the '275 patent is invalid and unenforceable. There is an actual controversy between the parties concerning GI's obligation under the GI License Agreement.

Count II: Declaratory Judgment That Baxter Owes No Royalties Under the Baxter License Agreement with Respect to the '275 Patent

34. Baxter incorporates all prior paragraphs of this complaint.

35. On information and belief, Columbia contends pursuant to the Baxter License Agreement that Baxter must pay royalties under the '275 patent. Baxter contends that it has no obligation to pay such royalties because the '275 patent is invalid and unenforceable. There is an actual controversy between the parties concerning Baxter's obligation under the Baxter License Agreement.

36. Baxter is entitled to and seeks to recoup any royalties paid to Columbia after the filing of this lawsuit. Baxter is entitled to recoup amounts paid under the Baxter License Agreement based on the '275 patent after Baxter gives notice to Columbia that Baxter is contesting the '275 patent's validity. This complaint gives such notice. Accordingly, Baxter is entitled to a declaratory judgment that Columbia must repay to Baxter the post-filing amounts paid under the Baxter License Agreement based on the '275 patent.

Count III: Declaration of Invalidity of the '275 Patent

37. Baxter incorporates all prior paragraphs of this complaint.

38. Baxter is entitled to and seeks a declaratory judgment that the '275 patent is invalid for non-statutory obviousness-type double-patenting because each of the claims of the '275 patent is the same as, or merely an obvious variant of, inventions claimed in other patents owned by Columbia, singly or in combination.

39. Baxter is further entitled to and seeks a declaratory judgment that the '275 patent is invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

40. There is an actual controversy between Baxter and Columbia concerning the validity of the '275 patent.

Count IV: Declaration of Unenforceability of the '275 Patent for Prosecution Laches

41. Baxter incorporates all prior paragraphs of this complaint.

42. Baxter is entitled to and seeks a declaratory judgment that the '275 patent is unenforceable by reason of prosecution laches, specifically, Columbia's unreasonable delay in prosecuting the applications that resulted in the '275 patent.

43. There is an actual controversy between Baxter and Columbia concerning the enforceability of the '275 patent.

Count V: Declaration of Unenforceability of the '275 Patent for Inequitable Conduct

44. Baxter incorporates all prior paragraphs of this complaint.

45. Baxter is entitled to and seeks a declaratory judgment that the '275 patent is unenforceable by reason of inequitable conduct, specifically, as set forth below, Columbia's (a) misleading statements to the examiner about whether its claims were patentable, (b) failure to make timely disclosure of a related application and its prosecution history, (c) failure to disclose the '636 patent and its prosecution history, and (d) failure to disclose statements made to Congress that were inconsistent with positions it took during prosecution of the '275 patent.

46. There is an actual controversy between Baxter and Columbia concerning the unenforceability of the '275 patent for inequitable conduct.

A. Misleading Statements Regarding the Patentability of Claims of the '275 Patent

47. As previously set forth, Columbia's '216, '665 and '017 patents contain the same original specification. All three patents expired in August 2000. To overcome double-patenting

rejections, Columbia filed terminal disclaimers that ended the terms of the '665 patent and the '017 patent on the expiration date of the '216 patent.

48. During prosecution of the '275 patent, in an office action dated February 3, 1998, the examiner rejected all pending claims for double-patenting over the issued claims of the '017 patent. These rejected claims were drawn to DNA constructs for transforming cells and, in the case of application claim 132, eukaryotic cells transformed using such constructs.

49. In response to the February 3, 1998 office action dated July 24, 1998, Columbia canceled claim 132. Columbia argued that the remaining DNA construct claims were not subject to the double-patenting rejection over the '017 patent. Thus, Columbia acknowledged that the claims that issued in the '017 patent relate to transformed CHO cells.

50. In an amendment filed June 14, 2001, Columbia added numerous new claims, some of which ultimately issued in the '275 patent. Columbia argued preemptively that the new claims were not subject to an obviousness-type double-patenting rejection. In each case, however, Columbia referred only to double-patenting in view of the '216 patent, not the '017 patent. Because the claims about which Columbia presented these arguments were newly submitted, Columbia did not make its assertions about double patenting in response to an examiner's rejection of claims; but rather to deter the newly assigned examiner from issuing double-patenting rejections.

51. In asserting that the new claims were not subject to double-patenting rejections over the '216 patent, Columbia misled the Patent Office by failing to draw the new examiner's attention to the claims of the '017 patent. The claims of the '017 patent, which provided the basis for double-patenting rejections in 1998 by the examiner at that time, are substantially

similar to the new claims Columbia added to the application leading to the '275 patent in June 2001 and could have provided a basis for a double-patenting rejection of the new claims.

52. Moreover, in view of Columbia's statements in the July 24, 1998 response conceding that the '017 patent relates to transformed CHO cells, Columbia was aware that the newly asserted claims, many of which were directed to transformed CHO cells, were vulnerable to double-patenting rejections over the '017 patent claims. Given the facts recited above, it is reasonable to infer that Columbia's misleading omission of Columbia's other issued patents, particularly the '017 patent, from its preemptive argument to the new examiner was a deliberate and intentional effort to draw attention away from the other grounds on which the claims could be rejected for double-patenting and thus to mislead the examiner.

53. Moreover, the arguments that Columbia raised were themselves substantially false and misleading. For example, Columbia stated that certain of the new claims were not vulnerable to double-patenting rejections because "none of the claims of the '216 make obvious a recitation of 'linked' [DNA I and DNA II]." In fact, issued claim 54 of the '216 patent recites transforming a eucaryotic cell "with a molecule which is ***formed by linking*** one of said foreign DNA I molecules to a DNA II molecule."

54. As another example, Columbia stated that other of the newly added claims were not vulnerable to double-patenting rejections because "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." However, issued claim 54 of the '216 patent (for example) recites transforming cells with a molecule formed by ***linking a*** DNA I to an ***amplifiable*** DNA II, and culturing the transformed cells under conditions "permitting survival or identification of eucaryotic cells which have acquired multiple copies of said amplifiable gene." Because DNA II is an amplifiable gene linked to DNA I, it is inherent in

the claim that the end result is both amplified DNA I and amplified DNA II. Therefore, contrary to Columbia's assertion, claim 54 does indeed make obvious a recitation that both DNA I and DNA II are amplified.

55. In an office action dated July 30, 2001, the examiner rejected a number of the newly added claims for obviousness-type double-patenting over claim 73 of the '216 patent.

56. In response to this office action, in a paper filed January 30, 2002, Columbia again stated that the claims were not obvious in view of the '216 patent for the same reasons it had asserted in its June 14, 2001 amendment. Like the June 14, 2001 amendment, the January 30, 2002 paper made no mention of the '017 patent or the fact that the claims of the '017 patent were substantially similar to the claims Columbia was then seeking.

57. Columbia's January 30, 2002 statement that the new claims should not be rejected over the '216 patent, while failing to draw the examiner's attention to grounds for rejection over the '017 patent, was misleading because it implied that the '216 patent was the only basis upon which a double-patenting rejection could be made. Upon information and belief, Columbia presented these statements with intent to mislead the patent examiner. The '275 patent is therefore unenforceable due to inequitable conduct in its prosecution.

B. Failure to Disclose Rejection of Substantially Similar Claims in '159 Application

58. As set forth above, on June 7, 1995, Columbia filed two continuation applications relying on the original disclosure filed in February 1980. One of these applications matured into the '275 patent. The other, Serial No. 08/477,159 ("the '159 application"), is still pending.

59. On information and belief, the '159 application includes claims directed to subject matter that is substantially similar to the subject matter claimed in the '275 patent.

60. On April 22, 1997, the examiner issued an office action rejecting claims in the '159 application for double-patenting over the '017, '216, and '665 patents. The claims were also rejected for failure to satisfy 35 U.S.C. § 112. Because these claims are substantially similar to claims that issued in the '275 patent, these rejections are highly material to the patentability those claims.

61. Despite the materiality of the '159 application and the rejections of claims substantially similar to the '275 patent claims in April 1997, Columbia did not make the existence of the '159 application of record in the '275 patent prosecution until May 6, 2002, nearly ***seven years*** into the co-pendency of the two applications and a mere three months before allowance of the claims of the '275 patent. Even then, Columbia failed to disclose to the examiner of the '275 patent the prior double-patenting rejections of substantially similar claims by a different examiner in the" '159 application. This contrary decision by another examiner was material to the patentability of the '275 patent claims.

62. Given the facts recited above, it is reasonable to infer that Columbia's unreasonable delay in disclosing the '159 application, as well as its failure to disclose the rejection of substantially similar claims by a different examiner in that case, was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

C. Failure to Disclose '636 Patent and Rejection of Substantially Similar Claims

63. As previously set forth, Columbia's '636 patent, which issued in 1992, was pending during the prosecution of several of the applications that ultimately led to the '275 patent. The claims of the '636 patent include claims directed to (a) processes for generating multiple copies of a foreign DNA I in eukaryotic cells and (b) product claims directed to

eukaryotic and mammalian cells into which foreign DNA I has been introduced by the claimed processes. These product-by-process claims of the '636 patent overlap in scope with at least claim 5 of the '275 patent and its dependent claims. The '636 patent was prosecuted by the same law firm that prosecuted the '216 patent and its continuation and divisional applications, including the '275 patent.

64. Columbia never disclosed the '636 patent to the examiner or made it of record during the prosecution of any of the '216, '665, '017 or '275 patents ("the '216 patent family"), despite the fact that the '636 patent could have provided a basis for a double-patenting rejection of various claims in the numerous applications that led to the '275 patent. The existence of the '636 patent was material to the patentability of claims Columbia prosecuted in the '216 patent family, including at least one claim that issued as part of the '275 patent.

65. On information and belief, the '636 patent file history includes rejections of claims that are substantially similar to claims pursued during prosecution of the '216 patent family, including the '275 patent. Thus, it is highly likely that a patent examiner evaluating the claims proposed in the applications leading up to the '275 patent would have wanted to be informed of the rejection, by a different examiner, of claims pursued in prosecution of the applications leading up to the '636 patent. Those rejections are therefore material to the patentability of the claims asserted during the prosecution of the '216 patent family, including the claims that ultimately issued in the '275 patent.

66. Notwithstanding the more than ***twenty years*** between the filing of the application that led to the '636 patent and the issuance of the '275 patent, and the many information disclosure statements Columbia filed in the prosecution of the '216 patent family during that

time period, Columbia failed to make the pendency, the issuance, or any part of the file history of the '636 patent of record in any of the applications that led to the issuance of the '275 patent.

67. As the owner of the '636 patent as well as the '275 patent, Columbia was aware of the materiality of the '636 patent and its file history to the '275 patent, as was its patent counsel, who prosecuted both the '636 and the '275 patents. Given the singular commercial and financial importance of the '216 patent family, it is reasonable to infer that Columbia's strategy for prosecuting that patent family and, in particular, the applications leading up to the '275 patent, did not arise from inattentiveness or accident. Given the facts recited above, it is also reasonable to infer that Columbia's failure to disclose the '636 patent or its file history during the prosecution of the '216 patent family was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

D. Failure to Disclose Statements to Congress Inconsistent With Positions Taken Before the Patent Office

68. As previously set forth, prior to the expiration date of its first three patents, Columbia lobbied Congress to obtain an extension on its patent term. On information and belief, Columbia made numerous statements to Congress that were inconsistent with positions it took in its concurrent prosecution of the '275 patent claims in the Patent Office. In its statements to Congress, Columbia emphasized the breadth and pioneering scope of the '216 patent. In contrast, in its statements to the Patent Office, Columbia argued that the scope of the '216 patent was much more limited. Columbia never disclosed to the Patent Office during prosecution of the '275 patent the inconsistent representations it made to Congress in 2000, in violation of its duty of candor to the Patent Office under 37 C.F.R. § 1.56.

69. Columbia also made inconsistent representations to Congress and the Patent Office on the issues of linked and unlinked cotransformation and amplification. Columbia told

Congress that the '216 patent covered both "linked" cotransformation and "unlinked" cotransformation. With respect to linked cotransformation, Columbia told Congress that under the '216 patent, "[t]he genes of interest can be joined together in a single DNA construct prior to their introduction into the cell of interest." Columbia also asserted to Congress that "[t]he Cotransformation process [claimed in the '216 patent] permit[s] the ... amplification of the gene of interest for the purpose of expressing large amounts of the protein it encoded."

70. In prosecuting the '275 patent, by contrast, Columbia characterized the claims of the '216 patent far more narrowly. For example, Columbia stated in June 14, 2001 and January 30, 2002 responses to office actions, that "none of the claims of the '216 make obvious a recitation of 'linked' [DNA I and DNA II]." Columbia also stated that "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." These statements were made to avoid obviousness-type double-patenting rejections over the '216 patent and were meant to persuade the examiner to read the '216 patent's claims with a narrow scope.

71. Columbia's assertions to Congress of the breadth of the '216 patent directly contradict its statements to the examiner of the '275 patent that the '216 patent claims must be read narrowly. Columbia never disclosed its statements to Congress to the Patent Office or advised the examiner that it had ever taken contrary positions as to the scope of the '216 claims. It may reasonably be inferred from these facts that Columbia's omission to disclose these inconsistent statements to the Patent Office was deliberately misleading. The '275 patent is therefore unenforceable for inequitable conduct.

Count VI: Declaration of Exceptional Case

72. Baxter incorporates all prior paragraphs of this complaint.

73. Baxter is entitled to and seeks a declaratory judgment that this is an exceptional case under 35 U.S.C. § 285 and that it is entitled to an award of reasonable attorneys' fees, costs, and expenses.

VI. REQUESTS FOR RELIEF

For the reasons set forth above, and for such other reasons that may be presented at trial, Baxter seek the following relief:

A. Judgment for Baxter against Columbia on all counts of this complaint;

B. Declarations that GI and Baxter have no obligation to pay further royalties to Columbia under the GI License Agreement and the Baxter License Agreement and that Baxter may recoup royalties previously paid to Columbia with respect to the '275 patent;

C. Declarations of invalidity and unenforceability of the '275 patent on the grounds set forth above;

D. Preliminary injunctive relief prohibiting the enforcement of the GI License Agreement and the Baxter License Agreement during the pendency of this action;

E. Permanent injunctive relief prohibiting Columbia from demanding any further royalties under the GI License Agreement and the Baxter License Agreement based on the '275 patent or on any pending continuation applications, continuations-in-part, or divisional applications of the patents recited in those agreements;

F. A declaration that this is an exceptional case under 35 U.S.C. § 285;

G. An award of reasonable attorneys' fees, costs, and expenses; and

H. Such other or further relief that the Court deems just.

DATED: November 12, 2003

BAXTER HEALTHCARE CORPORATION,

By its attorneys,

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